REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

The present invention is generally directed to bioprostheses. For example, the invention of claim one is directed to a bioprosthetic including a fixed natural tissue having an elastin content of at least about 30% by weight of the tissue and a support structure attached to the tissue that can include a polymeric material or a metallic material. The bioprosthetic can be, for example, a bioprosthetic heart valve, and the tissue included in the bioprosthetic can be, in one embodiment, vena cava tissue, for instance, porcine vena cava tissue.

In response to the Restriction Requirement, Applicants, through and by their representative, elect the claims of Invention I, claims 1-15, drawn to a bioprosthesis, for examination on the merits. Accordingly, claims 16-33 are hereby cancelled without traverse as directed to a non-elected invention.

Claims 1-15 and new claims 34-40 are presently pending in the application, including independent claims 1, 10, 34, and 38.

In the Office Action, claims 1-6 were rejected under 35 U.S.C. §102(e) as being anticipated by Yang (U.S. Application Publication 2003/0078659).

Yang is directed to methods of forming a graft element for reconstruction or repair of ligaments, tendons, or other body wall deficiencies (paragraph [0009]). For instance, the graft elements of Yang can be formed of luminal or tubular tissue of a human or animal (paragraph [0025]), that can first be split and then folded, wrapped, or rolled to form a graft element well-suited for ligament or tendon grafting (paragraph [0032]). While the tissue can be folded, rolled and secured so as to form a multi-layered element, the graft element of Yang does not include a support structure, and in particular a support structure formed of a polymeric or a metallic material attached to the tissue of the graft element, as is found in presently pending independent claims 1, 10, and 38. In addition, the graft element of Yang is not disclosed as a bioprosthetic heart valve, and in particular, is not disclosed as being suitable for forming a valve leaflet of a bioprosthetic heart valve as is found in presently pending independent claim 34. Accordingly, Applicants respectfully submit that the presently pending claims patentably define over Yang.

In the Office Action, claims 1, 2, 7 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Gregory (U.S. Patent No. 5,990,379).

Gregory is directed to prosthetic devices including elastin or an elastin-based materials, for example, prosthetic devices covered by the materials that can then be used as stents (col. 1, ll. 10-13). The elastin or elastin-based biomaterials of Gregory can be formed by polymerization, or formed to a suitable size and shape by molding. Optionally, the polymerized biomaterials can be cross-linked (col. 3, ll. 28-37). There are several examples given of synthetic elastin-based biomaterials that can be formed from starting proteins. Optionally, the elastin matrix of the invention can be formed via digestion of elastin-containing tissues such as arteries. (col. 4, ll. 15-39). For example, a starting tissue can be digested to remove cellular materials, proteins and fats from the native matrix. These methods can involve a combination of digestion methods and solvation means.(Col. 5, ll. 36-55). Accordingly, while the biomaterials of Gregory, can be formed from a starting material that is a natural tissue, this natural starting material is not found in the finished bioprosthesis. In particular, the biomaterial that is found in the prosthetic device is either an artificial tissue or a modified, digested natural tissue, rather than the natural tissues found in the presently pending claims. In particular, while the natural tissues of the present claims can be fixed in certain embodiments, they have not been digested, solvated, or otherwise modified so as to no longer be considered natural tissue. Accordingly, Applicants respectfully submit that the presently pending claims patentably define over Gregory.

In the Office Action, claim 1-4, 8-11, and 14 were rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen-Thien-Nhon (U.S. Patent No. 6,001,126).

Nguyen-Thien-Nhon is directed to a stentless aortic bioprosthesis including an aortic segment, right and left coronary artery segments, and a plurality of valve leaflets disposed within the aortic segment. (Col. 2, ll. 45-64). In particular, the aortic bioprosthesis is formed of a preserved segment of mammalian aorta and the donor animal's aortic valve leaflets (col. 4 – ll. 18-27).

Applicants respectfully submit that Nguyen-Thien-Nhon fails to disclose or suggest certain elements of the pending claims. For example, the natural tissues of the presently claimed bioprosthetics can be vena cava tissue, as is found in presently pending claims 5, 6, 10-11, 13-15, 36, and 38-40 or can be a natural tissue including at

least about 30% elastin by weight of the tissue, as is found in presently pending claims 1, 3-4, 7-9, 34-35, and 37. As discussed in the specification of the presently pending application (see, for example, the background section of the application, paragraphs [0036] – [0044], and Figure 5), the natural tissues of the presently claimed bioprosthetics have greater elastin content than tissues utilized in forming bioprosthetics in the past. For example, Svejcar, et al. (*Circulation Research*, Vol. XI, August 1962) and Goodall, et al. *(Journal of Vascular Surgery*, May, 2002) (both of which have been submitted in an Information Disclosure Statement concurrently with this Response), examine the elastin content of veinous tissue, and in particular aortic tissue, and found the elastin content to be 15.6% (Svejcar, et al., page 299) and 26% (Goodall, et al. page 940).

Similarly, valve cusps have been examined for elastin content by Lis, et al. (*Biochem. J.*, (1987)**244**, 597-603, submitted in an Information Disclosure Statement concurrently with this Response) and have been found to contain approximately 10% elastin content (Table 2, page 600). Accordingly, Applicants respectfully submit that an elastin content of at least about 30% cannot be assumed to be inherently present in the aortic tissue and valve leaflets included in the aortic bioprosthesis disclosed by Nguyen-Thien-Nhon, and as such, the presently pending claims patentably define over the reference.

In the Office Action, claims 1-3, 7-11, and 15 were rejected under 35 U.S.C. § 102(b) as being anticipated by Grassi (U.S. Patent No. 4,655,773).

Grassi is directed to a prosthesis for replacement of the bicuspid or mitral valve that can include a stent or support medium and the moving valve part. The material employed in fabricating the prosthesis can be either biological or synthetic, and in particular, the biological material can be glutaraldehyde-treated bovine pericardium (col. 1, ll. 44-49). Bovine pericardium, however, has not been found to include an elastin content of at least about 30% by weight, as is found in the natural tissues of presently pending claims 1, 3-4, 7-9, 34-35, and 37. For example, in addition to the results of research conducted by the present inventors, the results of which are illustrated in Figure 5 of the pending application, other research has shown bovine pericardium tissue to have an elastin content lower than about 30% by weight. For example, Wei, et al. (*Biomaterials*, **26**(2005) 1905-1913, submitted in an Information Disclosure

Statement concurrently with this Response), discloses bovine pericardial tissue as having an elastin content of about 4% by dry weight (page 1911, second full paragraph of the left column) and Schoen, et al. (*American Journal of Pathology*, **123**,134-145(1986), the abstract of which is submitted in an Information Disclosure Statement concurrently with this Response), teaches that pericardial protein of bovine pericardium is approximately 90% collagen (Abstract).

Accordingly, Applicants respectfully submit that an elastin content of at least about 30% cannot be assumed to be inherently present in the bovine pericardial tissue utilized in forming the bioprosthesis disclosed by Grassi, and as such, the presently pending claims patentably define over the reference.

As a final matter, various claims were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 31, and 33-39 of co-pending Application No. 10/722,142. Without commenting on the propriety of this rejection, Applicant agrees to submit a terminal disclaimer to the extent necessary at such time that the present application is otherwise in condition for allowance.

It is believed that the present application is in complete condition for allowance and favorable action, is therefore requested. Examiner Prebilic is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Response to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.

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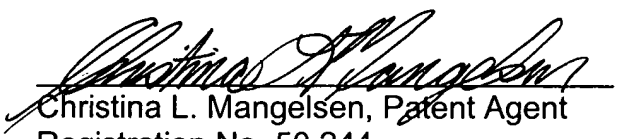
BY: 

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